REMARKS

Claims 1-12 remain under active prosecution in the present application. Claim 1 is presently amended.

By way of review, the present invention relates to a method by which biological materials may be detected in finished water. The method comprises the steps of analyzing a sample of finished water to determine the effects of the finished water on the agent to be detected, followed by suitable selection of a recognition element (such as an antibody) that permits detection in finished water. The present invention addresses the effects of water finishing on biological agents, wherein the effects of the finishing process on the molecular or chemical properties of the target agent is determined. This, in turn, permits appropriate selection of recognition elements to detect biological agents having altered binding properties. The present invention thereby allows detection of biological agents that would otherwise resist detection by standard methods, due to chemical or molecular alterations resulting from the finishing process.

In the subject Office Action dated June 14, 2006, the Examiner withdrew all rejections under 35 U.S.C. §102 in view of applicant's arguments. The Examiner has now rejected all claims on new grounds, citing the present invention as obvious under 35 U.S.C. §103 in view of Fritsch et al. (U.S. 2003/0108922) and Pyle et al. (U.S. 5,821,066). These rejections are addressed in detail below.

Claim Rejections - 35 USC § 103

The Examiner has rejected all pending claims under 35 U.S.C. § 103 as not patentable over Pyle et al (US 5,821,066) in view of Fritsch et al. (US 2003/0108922).

Claim 1 is presently amended to clarify, and place in proper form, the claim language of the instant application. In claim 1, "a" in reference to "biological agent" has been changed to read "the biological agent" such that the claim is in proper form. Claim 1 also now requires the steps of "analyzing a sample of finished water suspected of having a targeted biological agent and determining the effect said finished water has on the molecular recognition of the targeted agent by a molecular recognition agent, wherein the at least one first molecular agent that binds to the biological agent is selected as determined by the effect of the finished water. Support for this amendment may be found throughout the specification.[1] This amendment serves to better convey an important feature of the present invention, which is to determine how the constituents of treated water (*i.e.*, "finished water") change the molecular characteristics, and hence the binding properties (molecular recognition), of biological agents in water. The effects of finished water on molecular recognition of a targeted agent are described throughout the specification of the instant application. This amendment now makes clear that the "effect" of finished water on the biological agent encompasses alterations of the binding properties of the target agent that interfere with molecular recognition elements such as antibodies, and that the molecular recognition element is selected based on the changed binding properties.

The present amendments render the Examiner's rejections under 35 U.S.C. § 103 moot. The present amendments make clear that neither reference cited by the Examiner teaches the limitation of determining the effect of finished water on a biological agent and selecting a suitable molecular binding element based on those effects. As such, the prior art cannot be combined to teach all of the limitations of the pending claims, and the rejection under 35 U.S.C. § 103 cannot be sustained. The deficiencies of the prior art with respect to the presently amended claims are set forth in full below.

The Pyle Reference Fails to Teach or Suggest a Step of Determining the Effect of Finished Water on the Molecular Recognition of the Targeted Agent, Followed by Selection of an Appropriate Molecular Recognition Element

As noted by the Examiner, on p. 2 of the Office Action dated June 14, 2006, Pyle et al. does include the step of "determining the effect the (potable) water has on the targeted agent," wherein the "effect" is whether there are "viable or respiring cells" (see cl. 1). The Examiner has conceded that Pyle does not address "finished water." See p. 4 of the Office Action.

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[1] Support for this amendment may be found in the instant application at ¶0020: The "qualities. . . of finished water can interfere with the molecular recognition aspect. . . For example, the targeted agent can be altered so that the molecular recognition element can no longer recognize and/or capture the targeted agent"; ¶002: "... [A]lterations may render epitopes and/or nucleic acid sequences non-reactive towards the molecular recognition elements that have been developed for the unmodified version of the target agents"; ¶0022: discussing the effects of metal ions on reactions with molecular recognition elements; and ¶0024: ". . . pH levels in the testing solution can also interfere with molecular recognition. . ."

The clarifying amendments to claim 1 submitted herein render the rejection under 35 U.S.C. § 103 inapplicable. To sustain a rejection under § 103, the combined prior art references must teach or suggest all of the claim limitations. Applicant's amendment to claim 1 clarifies that the term "effect" is not limited to the viability of a biological or chemical agent, but rather, encompasses determination of any chemical, molecular, or structural alteration of a biological agent, regardless of viability of the agent, that affects molecular recognition (binding) by a molecular binding element. This clarification is supported throughout the specification, in which the myriad of ways in which the binding properties of contaminants in water can be altered (including presence of metal ions, pH, additives such as chlorine, *etc.*) are described. The amended claims now make clear that the present invention requires the step of determining these alterations in the target agent, and is not limited to determining viability of the agent. Pyle fails to disclose this step.

The amended claims now make clear that claim 1 also requires the step of selecting at least one molecular recognition element that specifically binds to the biological agent as determined by the effect of the finished water. This amendment now makes clear that the selection of a molecular recognition element is based on the alterations of the target agent, and the ability of the recognition element to bind, that result from the treatment process of finishing water. Pyle also fails to disclose this step.

In view of the above arguments, applicants respectfully submit that Pyle et al. fails to teach or disclose the claim limitation of "determining the effect said finished water has on the molecular recognition of the targeted agent" or "selecting at least one first molecular recognition element that specifically binds to the biological agent as determined by the effect of the finished water." Because the Fritsch reference is similarly deficient, as discussed below, that these references cannot be combined to form a valid basis for a rejection under 35 U.S.C. § 103.

The Fritsch Reference Also Fails to Teach or Suggest a Step of Determining the Effect Finished Water has on the Molecular Recognition of the Targeted Agent, or Selecting a

Molecular Recognition Element that Binds to the Agent as Determined by the Effects of the Water, and Therefore Cannot be Combined with Pyle to Render the Present Invention Obvious.

The Examiner has argued that the present invention is obvious in view of Pyle et al. and Fritsch et al. However, as both references fail to disclose the same limitations, they cannot be combined to render the present invention obvious.

Fritsch et al. is directed towards a method of detecting waterborne pathogens, wherein pathogens such as bacteria are immobilized on a surface, followed by non-covalent attachment of electrolabeling molecules. The molecules are then activated so as to generate a current that may be measured and used to detect concentration of pathogens. While Fritsch et al. contemplates detection of pathogens in "drinking water," this reference does not disclose or suggest the step of determining changes in molecular binding properties of the target pathogen caused by treatment of the water. The Examiner, at page 3 of the Office action dated June 14, 2006, concedes that Fritsch et al. does not teach this step. Similarly, Fritsch et al. does not teach the selection of a molecular recognition element based on alterations of the biological agent that results from the treatment process

Fritsch et al. is limited to disclosing a method of detecting pathogens and toxins in finished water without consideration of the effects of the water finishing process on the molecular recognition of the target agent. Because neither Fritsch et al. nor Pyle et al. disclose the above-described limitations of the presently claimed invention, these references cannot be combined to render the present invention obvious. Applicants therefore respectfully submit that the rejection under 35 U.S.C. § 103 has been overcome and must be withdrawn.

CONCLUSION

In view of the above amendments and remarks, applicants respectfully submit that the objection to the claims under 35 U.S.C. § 103 have been overcome and must be withdrawn.

The claims as currently pending are now in condition for allowance. Accordingly, reconsideration and allowance of those claims, as amended herein, is earnestly solicited. Applicants encourage the Examiner to contact their representative, Stephen R. Albainy-Jenei at (513) 651-6839 or salbainyjenei@fbtlaw.com.

The Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,

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